

United States District Court  
Southern District of Texas  
FILED

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION

OCT 30 2012

David J. Bradley, Clerk of Court

Vertos Medical Inc.

Plaintiff,

v.

Novitas Solutions, Inc.

Defendant.

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CIVIL ACTION NO. \_\_\_\_\_

**ORIGINAL VERIFIED COMPLAINT FOR MANDAMUS AND APPLICATION FOR  
INJUNCTIVE RELIEF AND TEMPORARY RESTRAINING ORDER**

Plaintiff Vertos Medical Inc. (“Vertos”) brings this action against Novitas Solutions, Inc. (“Novitas”), requesting mandamus and injunctive relief. In support, Plaintiff asserts:

**I. INTRODUCTION**

1. Novitas, a Medicare Administrative Contractor (“MAC”), has taken arbitrary and capricious action that will apply to all Texas Medicare beneficiaries who would otherwise benefit from the minimally invasive lumbar decompression (“*mild*”) medical procedure – a procedure that relies on Vertos’ proprietary and FDA cleared procedure kit for treating lumbar spinal stenosis. Specifically, Novitas denies Medicare coverage for the *mild* medical procedure to all Texas Medicare beneficiaries even when the procedure is medically reasonable and necessary. This Novitas action is an abuse of its discretion, and it causes Vertos immediate and irreparable harm. Vertos has no adequate remedy at law unless this Court grants immediate equitable relief.

2. TrailBlazer Health Enterprises, LLC (“TrailBlazer”) is the current MAC for Texas. Novitas is replacing TrailBlazer. TrailBlazer previously published a Local Coverage Determination (“LCD”) that denied Medicare coverage for *mild* throughout the State of Texas.

This TrailBlazer LCD was challenged by a Medicare beneficiary. In response to this challenge, TrailBlazer revised the LCD to properly provide Medicare coverage. Trailblazer has routinely been paying for the *mild* procedure since May 2012, provided the procedure was medically appropriate. Even so, Novitas - TrailBlazer's successor as the Texas MAC - has announced its intention to issue a non-coverage LCD that is materially identical to the TrailBlazer LCD policy that was challenged and revised pursuant to that challenge. Novitas has no discretion to instate a materially identical non-coverage LCD as the regulations preclude it from doing so. As such, Novitas is bound by TrailBlazer's action of revising its non-coverage LCD in the face of a legal challenge.

3. Vertos has no *administrative* channel to directly challenge Novitas' LCD because Vertos is neither a Medicare beneficiary nor a "supplier." Instead, Vertos must hope that Medicare beneficiaries or suppliers challenge erroneous coverage denials or LCDs. When Medicare beneficiaries and suppliers have challenged claim denials, these challenges routinely have been successful. Similarly, when a Medicare beneficiary challenged Trailblazer's non-coverage LCD, which applied to *mild*, it was successful. However, these successful appeals do not result in a final administrative order that permits federal court review. Now, although the regulations preclude it from doing so, Novitas plans to reinstate a materially identical non-coverage LCD for Texas, yet Vertos cannot administratively challenge this erroneous action. These efforts confirm that, as applied to the issue of coverage of *mild* in Texas, the Medicare administrative channel does not merely postpone Vertos' right to judicial review; it denies that right.

4. Vertos, therefore, requires and seeks equitable relief that will mandate that Novitas honor its non-discretionary duty to follow the law by maintaining the status quo, which is exempting *mild* from blanket non-coverage LCD.

## **II. PARTIES**

5. Vertos Medical Inc. is a corporation headquartered in Delaware with its principal offices in Aliso Viejo, Orange County, California.

6. Novitas Solutions, Inc. is a for-profit corporation headquartered in Pittsburgh, Pennsylvania. Novitas Solutions, Inc. is a wholly-owned subsidiary of Diversified Service Options - a holding company wholly-owned by Blue Cross Blue Shield of Florida, Inc. Novitas Solutions, Inc. may be served via its registered agent, C T Corporation System, 350 North Street Paul Street, Suite 2900, Dallas, TX 75201-4234. Novitas Solutions has been awarded the contract for Region JH which includes Texas. Consistent with its transition obligations, Novitas is responsible for publishing LCDs that will become effective in Texas and ultimately, will be responsible for processing Medicare claims arising from Texas.

## **III. JURISDICTION AND VENUE**

7. Vertos invokes the court's mandamus jurisdiction pursuant to 28 U.S.C. §§1361 and 1651.

8. Vertos also invokes the court's general federal question jurisdiction pursuant to 28 U.S.C. §1331; *see also*, 42 U.S.C. §§ 405 and 1395ii. Vertos asserts that it has no direct or indirect means of channeling its claims through the agency before seeking judicial review under the Medicare Act. The Medicare review channel as applied to Vertos does not postpone judicial review; it bars it. When the administrative channel bars federal court review as in this case, § 1331 provides federal question jurisdiction for effective review.

9. Additionally, this court has jurisdiction over this action pursuant to the Administrative Procedure, 5 U.S.C. §§ 551 *et seq.*

10. Venue in this judicial district is proper under 28 U.S.C. §1391(e). *Mild* is performed in this judicial district, and defendant's challenged conduct occurs within this judicial district.

#### IV. EVIDENCE

11. Plaintiff supports its claims and requested relief with this factual evidence:

- a) All factual assertions written in this verified complaint.
- b) The affidavit of Debra Parrish attached as EX A
- c) The affidavit of Tamara Fuller Rook attached as EX. B.
- d) The affidavit of Allen W. Burton attached as EX. C.
- e) The non-coverage LCD published by Novitas, which is at issue in this case, attached as EX. D.
- f) The Centers for Medicare & Medicaid Services ("CMS") Transmittal MM7443, *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2011-Transmittals.html>, attached as EX. E.
- g) CMS Transmittal R2234CP *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2011-Transmittals.html>, attached as EX. F.
- h) Trailblazer's non-coverage LCD for the Medicare jurisdiction covering Texas, attached as EX. G.
- i) The redacted complaint of a Medicare Beneficiary challenging Trailblazer's non-coverage LCD for the Medicare region covering Texas, attached as EX. H.
- j) Trailblazer's revision to the non-coverage LCD, attached as EX. I.

## V. BACKGROUND

### **Novitas has no discretion to reinstate a non-coverage LCD in Texas.**

12. In July 2011, TrailBlazer, the current Texas MAC, published an LCD that denied coverage for all services billed using Category III CPT billing codes, because they were allegedly investigational, unproven or experimental. EX. G. The *mild* procedure, billed with code CPT 0275T, fell within the “Category III” non-coverage LCD, and TrailBlazer did not exempt it despite overwhelming evidence of its safety and effectiveness. In May 2012, this TrailBlazer LCD was challenged by a Medicare beneficiary on the basis that the LCD was not supported by evidence and not reasonable under Medicare regulations. EX. H. Faced with this challenge, TrailBlazer revised its non-coverage LCD for *mild* and expressly exempted *mild* from the Category III non-coverage LCD. EX. I.

13. When, as here, a MAC revises a LCD when it is under legal challenge, the law construes Trailblazer’s revision as a finding by an Administrative Law Judge that the LCD was unreasonable. 42 C.F.R. §§ 426.420(b), 426.460(b).<sup>1</sup>

The contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis (such as additional evidence) than what the ALJ evaluated.

42 C.F.R. § 426.463; Medicare Program Integrity Manual, Chapter 13, §13.13.15 (same).

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<sup>1</sup> “A contractor may revise an LCD under review to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD. Revising an LCD under review to remove the LCD provision in question has the same effect as a decision under § 426.460(b).” 42 C.F.R. §426.420(b). Per § 426.460(b) “Not valid under the reasonableness standard. If the ALJ finds that the provision or provisions of the LCD named in the complaint is (are) invalid under the reasonableness standard, and no appeal is filed by the contractor or CMS..., the contractor...must provide...(2) coverage determination relief. If neither the contractor nor CMS appeals the ALJ decision..., the contractor implements the ALJ decision within 30 days. Any change in policy applies prospectively to requests for service or claims filed with dates of service after the implementation of the ALJ decision.” *Id.* at § 426.460(b).

14. Stated another way, a MAC is now precluded from reinstating the *mild* non-coverage LCD in Texas without cause. *See* 42 C.F.R. §§ 426.420(b), 426.460(b), 426.463. TrailBlazer has never tried to reinstate *mild* in its Category III non-coverage LCD.

15. The TrailBlazer coverage revision made in the face of a challenge may not be reinstated in Texas without a showing of reasoned justification. In addition to the regulatory authority, this fact is also compelled by collateral estoppel principles, and, further, supported by the Medicare Program Integrity Manual §13.13.15 that prohibits a MAC from re-instating a non-coverage provision found unreasonable.

16. Even so, in June 2012, one month after TrailBlazer revised the LCD to provide coverage for *mild*, Novitas as the MAC succeeding TrailBlazer, announced its intent to reinstate non-coverage for *mild* on precisely the same basis that Trailblazer mistakenly did, i.e., solely because the procedure was billed using a Category III CPT code.

17. Novitas published LCD ID Number L32691 that became effective in Texas on October 29, 2012 for Medicare Part A and will become effective on November 19, 2012 for Medicare Part B. The LCD states that “Category III codes will be automatically denied as investigational unless specifically addressed in another LCD.” Ex. D, p. 1. The Novitas LCD fails to exempt *mild* just as TrailBlazer previously had incorrectly done. Novitas provided no justification for ignoring the binding effect of TrailBlazer’s decision to revise its non-coverage LCD when it was challenged. In fact, Novitas’ efforts to adopt an LCD with a non-coverage provision relating to *mild* are an arbitrary and capricious act that it has no discretion to take.

**LCD’s must be developed based on best available evidence.**

18. LCD’s require that a MAC consider the peer-reviewed literature and opinion of the relevant medical community. Specifically, the Medicare Program Integrity Manual provides

that “Contractor LCDs shall be based on the strongest evidence available.” Medicare Program Integrity Manual (“MPIM”) Ch. 13 § 13.7.1 *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html>.

Additionally, the manual provides the following:

In order of preference, LCDs should be based on: [1] Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and [2] General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on: [a] Scientific data or research studies published in peer-reviewed medical journals; [b] Consensus of expert medical opinion (i.e., recognized authorities in the field); or [c] Medical opinion derived from consultations with medical associations or other health care experts.

*Id.* There is no indication that Novitas followed this standard in developing its LCD.<sup>2</sup> If it had, it could not have denied coverage to *mild*. All factors that a MAC should consider compel coverage as TrailBlazer’s LCD revision acknowledged.

19. This is particularly true where *mild* routinely has been performed and covered and is part of the standard of care in Texas and all other states in the region since May 2012. *See* EX. I.

### **CMS’ published guidance supports Medicare coverage for *mild*.**

20. Effective July 1, 2011, CMS issued a directive to MACs that the *mild* Category III CPT code 0275T is a payable code. EX. E, p. 3; EX. F, p. 2; *see also* EX. E, p. 4 (specifying payment information for CPT code 0275T); EX F, p. 3 (same). This CMS directive was ignored

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<sup>2</sup> “No Evidence To Support an LCD/NCD

Comment: We received several comments stating that where no record exists to support an LCD/NCD, the beneficiary should not have to introduce new evidence.

Response: We expect that it would be a rare event that no record exists. In that rare event, we agree with the commenter. We have made changes to clarify that, in the rare event that no evidence exists to support an LCD..., we will either voluntarily retire/withdraw that policy, or request the ALJ/Board to strike down the applicable provision(s) of the policy, whichever the more expeditious option.” 68 Fed. Reg. 63692-01

by Novitas. If Novitas followed the CMS directive, it could not have reasonably published a blanket LCD denial of coverage for *mild*.

21. If *mild* were experimental and investigational, as the Novitas LCD indicates, then CMS would have been statutorily prohibited from issuing the foregoing directive to its MACs.

**Nine Administrative Law Judge decisions originating out of Texas’ Medicare Region support Medicare coverage for *mild*.**

22. Numerous Medicare beneficiaries successfully challenged TrailBlazer’s coverage denials for *mild* during the period before Trailblazer revised its non-coverage LCD. EX. A.

23. Nine CMS Administrative Law Judge (“ALJ”) decisions found that *mild* was a reasonable and necessary procedure covered by Medicare.<sup>3</sup> To reach that finding, the ALJ’s necessarily found that *mild* was a procedure covered by Medicare. If the *mild* procedure were experimental or investigational, the CMS ALJs would have been barred from deeming the procedure to be a covered Medicare benefit.

24. None of these decisions were appealed. All demonstrate that a blanket denial of Medicare coverage for *mild* is unsupportable. See EX A.

**Denial of coverage is particularly inequitable in the case of *mild*.**

25. Novitas’ wrongful denial of coverage for *mild* is particularly inequitable given that *mild* is beneficial for patients and reduces health care costs.

26. Lumbar spinal stenosis is a source of low back and leg pain; the condition results from the narrowing of the central lumbar canal. This canal narrowing causes pain when it

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<sup>3</sup> To receive an ALJ decision, a beneficiary or supplier had to do the following: (a) submit the claim to Trailblazer, (b) ask Trailblazer to reconsider its denial of the claim (c) appeal Trailblazer’s denial of the claim to a “Qualified Independent Contractor” (“QIC”), (d) appeal the QIC’s decision to an ALJ, where the beneficiary or supplier may obtain a hearing and an adjudication on the merits. 42 C.F.R. § 405.904.

squeezes or compresses the nerve roots that run through the canal. Regrettably, the condition is wide-spread, serious, chronic, and progressive. EX. C.

27. Historically, the treatment options for this condition were limited to invasive surgical procedures; for an example, laminectomy, bilateral laminectomy, and, spinal fusion. EX. C.

28. Vertos' *mild* is a ground-breaking treatment option that is less invasive and less costly than traditional surgeries. EX. C.

29. A physician performs the *mild* procedure through either one or two, depending on the patient, incisions in the back that are about the size of a baby aspirin. Imaging guides this targeted procedure for removing bone that is compressing the nerves with a minimum disruption of muscle and skeletal tissues. It is normally an out-patient procedure, performed under local anesthesia, and the surgical "wound" can be closed with a band aid. *See* EX. C.

30. FDA cleared the surgical kit for *mild* in February 2010, finding it safe and effective for the procedure. EX. C.

31. The procedure is generally accepted by the relevant medical community and has been widely and successfully used. EX. C.

32. Vertos' *mild* is the subject of at least twelve peer-reviewed publications in the medical literature that conclude it is safe and effective for the treatment of lumbar spinal stenosis. EX. C.

**Novitas' administrative action will result in irreparable harm to Vertos for which it has no administrative remedy.**

33. Novitas' erroneous implementation of the non-coverage LCD poses imminent, irreparable harm to Vertos.

34. The *mild* devices constitute 100% of Vertos' revenue, and the vast majority of *mild* patients are Medicare beneficiaries. As a result, wrongful Medicare denials result in a significant loss of revenue to Vertos, potentially exceeding millions of dollars. EX. B.

35. Novitas non-coverage LCD completely denying Medicare coverage for the state of Texas multiplies this problem by eroding investor confidence. Vertos' future is tied to investor confidence. EX. B. The arbitrary and capricious reversion by Novitas to a non-coverage LCD imminently threatens the loss of the more than \$46 million dollars current investors have made to successfully develop and commercialize *mild*. *Id.*

36. The potential combination of Vertos' loss of revenue and loss of investors would cripple Vertos. EX. B.

37. Vertos, however, has no direct access to the administrative appeal channel. The administrative appeal channel does not postpone Vertos' right to judicial review but denies it.

38. Vertos has no direct access to the administrative review process despite the fact that it is directly affected by Medicare coverage decisions. It is within the zone of interest of Medicare coverage determinations, but has no direct access to the review channel.

39. Only a Medicare beneficiary can administratively challenge an LCD.<sup>4</sup> If Medicare coverage for *mild* is denied, the patient may challenge the denial.

40. Medicare beneficiary challenges demonstrate that the administrative review channel does not simply postpone Vertos' right to judicial review; it denies that right. Despite the virtually unanimity of success obtained by Medicare beneficiaries and providers, a final

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<sup>4</sup> "An aggrieved party may initiate a review of an LCD by filing a written complaint with the office designated by CMS..." 42 C.F.R. § 426.400(a). An "aggrieved party" is "a Medicare beneficiary, or [in some circumstances,] the estate of a Medicare beneficiary..." *Id.* at § 426.110.

administrative ruling that is reviewable by a federal court is unrealistic as a practical matter. The successful challenges are ignored rather than appealed.<sup>5</sup>

41. This disregard for the successful appeals is demonstrated by the Novitas LCD that is challenged here. The current MAC revised its non-coverage LCD when faced with a challenge, and this revision became binding absent cause. But within a month, the replacement MAC, Novitas, simply reinstated the non-coverage LCD in Texas without even attempting to show cause. The administrative channel denies Vertos a right to judicial review from this arbitrary and capricious conduct. Vertos suffers irreparable harm that can be corrected only by recourse to this Court.

## **VI. CAUSES OF ACTION**

### **COUNT ONE: MANDAMUS**

42. Plaintiff hereby incorporates by reference paragraphs 1 to 41 herein.

43. Novitas must perform its duties pursuant to legal authority. *See*, 42 U.S.C. § 1395kk-1(b)(2). Mandamus relief should be issued here where (1) Vertos has a clear right to relief; (2) Novitas has a clear duty to act; and (3) No other adequate remedy exists. *Wolcott v. Sebelius*, 635 F.3d 757, 768 (5th Cir. 2011). Here, a Medicare beneficiary challenged Trailblazer's LCD, which blanketly denied coverage for *mild*. EX. H. Faced with that challenge, Trailblazer revised its non-coverage LCD as applied to *mild*. EX. I. Consequently, the MAC was bound by law not to exclude the *mild* procedure from Medicare. 42 C.F.R. §§ 426.420(b), 424.460(b), 426.463. Novitas has no discretion to revise the existing Texas LCD without cause. 42 C.F.R. §§ 426.420(b), 424.460(b), 426.463; *see also* 68 Fed. Reg. 63692-01. Instead, Novitas has a non-discretionary duty to perform its obligations under law, which is to

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<sup>5</sup> *See DeWall Enterprises, Inc. v. Thompson*, 206 F. Supp. 2d 992, 998 (D. Neb. 2002) (Plaintiff demonstrating that successful appeals were ignored rather than appealed).

maintain the status quo by not reinstating the non-coverage LCD related to *mild*. Finally, Vertos has no adequate remedy. Even though a Medicare beneficiary previously successfully challenged a materially identical LCD, Novitas simply ignored the binding effect of that challenge. Vertos cannot administratively challenge Novitas' arbitrary and capricious action of reinstating the non-coverage LCD. Novitas' arbitrary and capricious non-coverage LCD in Texas must be set aside.

44. TrailBlazer revised the current non-coverage LCD in the face of a legal challenge. The law construes such a revision as a finding on the merits that the LCD was unreasonable. 42 C.F.R. §§ 426.420(b), 424.460(b). Accordingly, Novitas has no discretion to reinstate the LCD. 42 C.F.R. §426.463. This conclusion is supported by relevant administrative authority, collateral estoppel and the evidence offered in this Complaint. Moreover, the Fifth Circuit has found that mandamus jurisdiction exists if the action is an attempt to compel an officer or employee of a United States agency to perform an allegedly non-discretionary duty owed to the plaintiff. *Wolcott*, 635 F.3d at 766 (5th Cir. 2011) (citing *Ingalls Shipbuilding, Inc. v. Asbestos Health Claimants*, 17 F.3d 130, 132 (5th Cir. 1994)).

45. Novitas has presented no evidence or rationale for reinstating a blanket coverage denial that, in May of this year, was revised in response to a Medicare beneficiary's challenge. To the contrary, the extant evidence – including, but not limited to, twelve peer-reviewed publications in the medical literature and nine ALJ decisions – supports the position now taken by TrailBlazer when it exempted *mild* from a non-coverage LCD. The same position is supported by the FDA, the CMS and the AMA.

46. In light of the absence of evidence demonstrating that *mild* can never be covered by Medicare, Novitas has a non-discretionary duty to exempt *mild* from Novitas' Category III

non-coverage LCD effective in Texas. 42 C.F.R. §§ 426.420(b), 424.460(b), 426.463; *see also* 68 Fed. Reg. 63692-01.

47. Vertos asks the Court to protect the status quo and compel Novitas to follow the law by exempting *mild* from Novitas' Category III non-coverage LCD effective in Texas.

### **COUNT TWO: INJUNCTIVE RELIEF**

48. Plaintiff hereby incorporates by reference paragraphs 1 to 47 herein.

49. As alleged above, Novitas has no discretion to reinstate Trailblazer's non-coverage LCD as applied to the *mild* billing code absent evidence additional to that relied on by Trailblazer in support of the non-coverage LCD. Novitas has not provided any additional basis on which to reinstate the non-coverage LCD. The court must restrain Novitas from reinstating a non-coverage LCD that was revised in the face of a challenge.

50. A party seeking a temporary restraining order or preliminary injunction must prove each of the following elements: (1) that there is a substantial likelihood that the movant will prevail on the merits; (2) that there is a substantial threat that irreparable harm will result if the injunction is not granted; (3) that the threatened injury outweighs the threatened harm to the defendant; and (4) that the granting of the preliminary injunction will not disserve the public interest. *Clark v. Prichard*, 812 F.2d 991, 993 (5th Cir. 1987); *see also, Janvey v. Alguire*, 647 F.3d 585, 595 (5th Cir. 2011); *DeWall Enterprises, Inc.*, 206 F. Supp. 2d at 1000-01; FED. R. Civ. P. 65(b).

51. Vertos' has demonstrated a likelihood of success on the merits by Trailblazer's action of revising its non-coverage LCD in the face of a challenge. Novitas provided no justification for ignoring the binding effect of Trailblazer's decision as it is required to do. *See* 42 C.F.R. §§ 426.420(b), 424.460(b), 426.463; *see also* 68 Fed. Reg. 63692-01. Furthermore, at

least twelve peer-reviewed publications in the medical literature have found that *mild* is a safe and effective procedure. Further, numerous ALJ's have found that *mild* is a procedure covered by Medicare, provided it is reasonable and necessary for the particular patient beneficiary.

52. Vertos is irreparably harmed by wrongful Medicare coverage denials. Vertos will lose substantial income from a blanket denial of Medicare coverage for *mild*. The wrongful denials result in loss of sales. Such loss of sales result, in part, because of loss of physician confidence in their ability to be paid. This damage is multiplied by the Novitas LCD blanket denial in Texas that is challenged in this case. Vertos' future is tied to investor confidence, and the continued wrongful denials of Medicare coverage erode investor confidence. The arbitrary and capricious reversion by Novitas to a non-coverage LCD imminently threatens the loss of the more than \$46 million dollars current investors have made to successfully develop and commercialize *mild*. EX. B.

53. The threatened injury to Vertos outweighs the threatened harm to Novitas. Vertos is only asking the Court to require Novitas to follow the procedures that preclude Novitas from reinstating the *mild* non-coverage LCD in Texas without cause. Vertos merely is requesting the Court to order Novitas to follow the law. 42 C.F.R. §§ 426.420(b), 424.460(b), 426.463. Trailblazer followed these procedures previously. Novitas arbitrarily seeks to change the MAC's position. As one court stated, Medicare is not harmed by the consistent interpretations of Medicare regulations. *See DeWall*, 206 F. Supp. 2d at 1002. The granting of the injunction will not disserve the public. Rather, the public will benefit from the consistent application of Medicare regulations.

54. Accordingly, upon hearing, Vertos requests that a temporary restraining order be issued and remain in effect until such time as a temporary injunction can be entered to protect

Vertos' interests, which enjoins Novitas, its officers, agents, servants, employees, attorneys, and all other persons acting in concert or participation with any of them who receive actual notice of the order by personal service or otherwise from imposing an LCD that categorically denies coverage of *mild*.

**COUNT THREE: VIOLATION OF PROCEDURAL DUE PROCESS**

55. Medicare offers no administrative channel to meaningfully challenge a MAC LCD, denying coverage for *mild*. As a result, the channeling requirement, if applied, does not simply postpone judicial review; it precludes that review. This violates the United States Constitution's Fifth Amendment Due Process Clause.

**VII. REQUESTED RELIEF**

WHEREFORE, Plaintiff requests:

56. An order mandating Defendant to perform its non-discretionary duty to exempt *mild* from its LCD denying Medicare coverage for Category III codes;

57. An order precluding Novitas from imposing an LCD that denies coverage of *mild*;

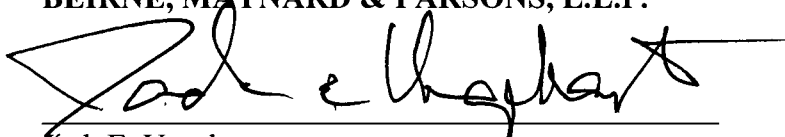
58. An order requiring Novitas to continue paying for *mild* services when medically appropriate;

59. Legal fees and costs of suit incurred by Plaintiff; and

60. Such other relief as this Court may consider appropriate.

Respectfully submitted,

**BEIRNE, MAYNARD & PARSONS, L.L.P.**

A handwritten signature in black ink, appearing to read "Jack E. Urquhart", is written over a horizontal line.

Jack E. Urquhart

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UNITED STATES DISTRICT COURT  
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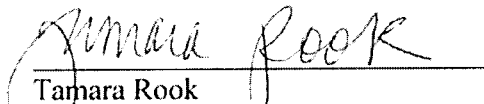
CIVIL ACTION NO. \_\_\_\_\_

**VERIFICATION**

**BEFORE ME**, the undersigned Notary Public, on this day personally appeared Tamara Rook, Vice President, Reimbursement at Vertos Medical, Inc., who, being by me duly sworn on oath according to law, did depose and state the following:

1. My name is Tamara Rook, and I am a duly authorized representative of Vertos Medical Inc., plaintiff in the above-entitled and numbered cause. I have read the above **ORIGINAL VERIFIED COMPLAINT FOR MANDAMUS AND APPLICATION FOR INJUNCTIVE RELIEF AND TEMPORARY RESTRAINING ORDER**. The factual statements in such pleading are within my personal knowledge, with the exception of the affidavits of Allen W. Burton and Debra Parrish, on which I relied based upon information and belief. The factual statements contained in such pleading are true and correct to the best of my knowledge.

**VERTOS MEDICAL INC.**

  
\_\_\_\_\_  
Tamara Rook  
Vice President, Reimbursement, Vertos Medical Inc.

SUBSCRIBED AND SWORN TO BEFORE ME on October 30, 2012, to certify which witness my hand and official seal.

My Commission Expires:



  
\_\_\_\_\_  
NOTARY PUBLIC IN AND FOR  
THE STATE OF CALIFORNIA